R E M A R K S

Page 10 of the specification was amended to correct a minor clerical error.

Claim 5 was amended to include features from claims 1, 6 and 19. The amendments are supported in the specification by page 10, line 14 ("COX-2"), page 11, lines 16 to 18 and by the Examples on pages 8 to 11.

The present claims are directed to a method for detecting colon cancer wherein the tumor marker is COX-2. The method comprises: a) homogenizing collected feces in the presence of an RNase inhibitor to prepare a suspension thereof, without separating cell components from the feces; b) extracting RNA from the suspension from step a) to provide extracted RNA; c) carrying out reverse transcription on the extracted RNA from step b) to provide cDNA; d) amplifying the cDNA from step c); and e) detecting the amplified COX-2 from step d).

Claims 1 to 5, 13 to 14, 17 to 19 and 21 to 22 were rejected under 35 USC 102 as being anticipated by Alexander and Raicht (1998), Digestive Diseases and Sciences, Vol. 43, No. 12, pp. 2652-2658, as evidenced by Ultraspec™-II RNA, Isolation System, Biotecx Bulletin, No. 28, 1993, for the reasons set forth in item no. 8 on pages 4 to 7 of the May 2, 2008 Office Action.

Claims 6, 15, 16 and 20 to 22 were not included in the 35 USC 102 rejection.

As discussed above, the feature of claim 6 ("COX-2") was introduced into claim 5.

As admitted at the middle of page 7 of the May 2, 2008 Office Action, Alexander and Raicht do not teach a method wherein the tumor marker is COX-2.

It is therefore respectfully submitted that claim 5 and the claims dependent thereon are not anticipated by Alexander and Raicht.

Withdrawal of the 35 USC 102 rejection is therefore respectfully requested.

Claims 6, 20 and 23 were rejected under 35 USC 103 as being unpatentable over Alexander and Raicht (1998), Digestive Diseases and Sciences, Vol. 43, No. 12, pp. 2652-2658, as evidenced by Ultraspec™-II RNA, Isolation System, Biotecx Bulletin, No. 28, 1993, in view of Sano et al., (1995), Cancer Research, 55: 3785-3789 for the reasons set forth in item no. 10 on pages 7 to 10 of the May 2, 2008 Office Action.

Claims 15 and 16 were rejected under 35 USC 103 as being unpatentable over Alexander and Raicht, (1998), Digestive Diseases and Sciences, Vol. 43, No. 12, pp. 2652-2658, as evidenced by Ultraspec™-II RNA, Isolation System, Biotecx Bulletin, No. 28, 1993, in view of Godfrey et al. (USP 7,101,663) for the reasons indicated in item no. 11 on pages 8 to 10 of the May 2, 2008 Office Action.

It was admitted in the May 2, 2008 Office Action that Alexander and Raicht do not teach that amplifying cDNA is carried out by a nested PCR.

As discussed above, Alexander and Raicht do not teach a method wherein the tumor marker is COX-2.

Sano et al. show enhanced expression of the COX-2 gene in colon cancer tissues and suggest new avenues for therapy.

However, Sano et al. do not disclose any experimental result using the COX-2 gene as a tumor marker for detecting colon cancer by using feces.

The Ultraspec™-II RNA Isolation System, Biotecx Bulletin, No. 28 (1993) is directed only to a kit for the isolation of total RNA.

USP 7,101,663 is directed only to a technique for carrying out RT-PCR.

None of the references teach or suggest any usefulness of COX-2 as a tumor marker for detecting colon cancer.

It is respectfully submitted that one of ordinary skill in the art would not consider to combine the references in the manner as set forth in the May 2, 2008 Office Action. Even assuming *arguendo* that the references are combinable, for the reasons discussed above, it is respectfully submitted that combining the references as set forth in the May 2, 2008 Office Action would not lead to applicant's present claims.

It is respectfully submitted that the comparative data set forth in Example 1 on page 9, lines 15 to 31 in the present specification, as described hereinabove regarding the sensitivity and the specificity of three colon cancer detecting methods, provide a showing of unexpected results for the COX-2 detecting method according to the presently claimed invention.

As described on page 9, lines 23 to 28 of the present specification, "COX-2 was detected in 27 cases among the 30 colon cancer cases, but was not detected in any of 22 cases in the control group" (**sensitivity: 90%, specificity: 100%**) [emphasis supplied].

On the other hand, CEA (carcinoembryonic antigen) (i.e., known as a tumor marker for colon cancer) was detected in all cases among 30 colon cancer cases, and in 21 among 22 cases in a control group (see page 9, lines 19 to 21 of the present specification).

Further, in a conventional immunological fecal occult blood test, 23 among 28 colon cancer cases and 3 among 22 control cases were positive (**sensitivity: 82.1%, specificity: 86.3%**) (see page 9, lines 29 to 31 of the present specification).

The above results are summarized as follows:

	Marker	Sensitivity (%)	Specificity (%)
Present Invention	**COX-2**	**90.0 (27/30)**	**100.0 (22/22)**
Conventional Methods	CEA	100.0 (30/30)	4.5 (1/22)
	occult blood	82.1 (23/28)	86.3 (19/22)

The conventional fecal occult blood test has a rather low sensitivity and low specificity (the sensitivity: 30 to 90%, the specificity: 70 to 98%) (see page 1, lines 29 to 31 of the present specification).

CEA, also expressed in colon cancer, has a high sensitivity, but a quite low specificity.

In contrast thereto, the sensitivity and the specificity of the presently claimed invention is far superior to each of CEA and occult blood.

None of the cited references describe or suggest that COX-2 has a high sensitivity and a high specificity in a method for detecting colon cancer. It is respectfully submitted that a person of ordinary skill in the art would not expect the aforesaid desirable results afforded by employing COX-2 as a colon cancer tumor marker.

Thus, "the method of the present invention is clinically very useful as a novel, non-invasive screening method with high specificity and high sensitivity (see page 11, lines 16 to 18 of the present specification).

As seen in Example 2 on pages 10 to 11 of the present specification, while no PCR products were obtained from a sample obtained by using the method of Alexander and Raicht, desired products containing high molecular weight RNAs, such as 28s and 18s rRNAs were obtained from the sample obtained by using the method according to applicant's present claims.

It is respectfully submitted that since the presently claimed invention provides unexpected results that are not afforded by the cited references, applicants' present claims patentably distinguish over the references singly or combined in the manner as set forth in the Office Action.

Withdrawal of each of the 35 USC 103 rejections is thus respectfully requested.

Reconsideration is requested. Allowance is solicited.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

Respectfully submitted,

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